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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,362

04/13/2006

Alexandre Laurent

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08/07/2008

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

08/07/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/541,362	Applicant(s) LAURENT ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 20 is/are rejected.
- 7) ☒ Claim(s) 6-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 Sept. 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 4 February 2008, in the matter of 10/541,362.

Applicants' arguments filed 4 February 2008 have been fully considered but they are deemed moot in light of the following remarks.

The previous Office Correspondence, mailed 3 January 2008, required restriction between Group I (claims 1-17 and 20), which is directed to composition claims, and Group II (claims 18 and 19), which is directed to method (e.g. "use") claims. However, it has been brought to the attention of the Examiner that the version of claims, which formed the basis for the previous restriction requirement, was not the most current set of claims provided by Applicants. Applicants properly filed an English translation annex to the International Preliminary Examination Report (Article 34) wherein claims 18 and 19 had been amended to reflect composition claims rather than method claims. Therefore, in light of the newly discovered amended claims, the Examiner hereby **withdraws** the requirement for restriction and joins claims 18 and 19 with the remaining claims for prosecution on the merits.

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Claims 1-20 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement filed 16 September 2005 is acknowledged and has been reviewed.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claim 5 is objected to because of the following informalities: the shorthand representation of the units “(m/V)” is used in the claims and specification without further definition. The Examiner broadly and reasonably interprets, for the purposes of examination on the merits, that the recitation reads as “mass per volume”.

Appropriate correction is required.

Claims 6-19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6-17 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term “injectable”, which is interpreted by the Examiner as meaning “capable of being injected” renders the claim indefinite since it is not clear whether injection of the composition is the inventive route of administration.

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The remaining claims are rejected as being dependent from the rejected independent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-4 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakashio et al. (USPN 4,029,616).

The instant claim 1 is drawn to a polymer-based composition comprising: a linear polymer which is water-insoluble, yet soluble in a water-miscible solvent, at least one water-insoluble, hydrophilic crosslinked polymer, and at least one biocompatible, and a water-miscible solvent (claim 1). Claims 2-4 further limit the linear polymer. That the instantly claimed composition takes on the form of a solution or a suspension by virtue of combining said linear polymer (e.g. HPMA and acrylonitrile) with an ethanol solvent and a hydrophilic crosslinked polymer (e.g. HEMA), is a property which is inherently taught by the practiced composition of Nakashio et al., since "products of identical chemical composition cannot have mutually exclusive properties" (see MPEP § 2112.01(II)).

Nakashio et al. teach a polymer composition comprising at least one water-insoluble linear polymer, such as a mixture (e.g. copolymer) of hydroxypropyl methacrylate (HPMA) and acrylonitrile, and at least one biocompatible, water-miscible solvent such as ethanol

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(claims 1-4). Nakashio further teaches that the aforementioned HPMA and acrylonitrile ethylenic polymer may further comprise a water-insoluble, hydrophilic crosslinked polymer such as hydroxyethyl methacrylate or HEMA (claim 2).

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Bajaj et al.

(*Journal of Polymer Science: Polymer Chemistry Edition*).

Bajaj et al. teach the copolymerization of acrylonitrile (AN) with 3-chloro, 2-hydroxy-propyl methacrylate (CHPMA) into either a solution or a suspension using either of the water-miscible solvents: de-ionized water or de-ionized water/acetone (see Synopsis, Introduction and Copolymerization).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashio et al. (USPN 4,029,616).

The instant claims are drawn to a polymer-based composition as discussed above. Claim 5 further limits the amount of the linear polymer in the composition. The instant independent claim 20 is directed to a linear copolymer-based solution comprising at least one linear copolymer of hydroxypropyl methacrylate and of acrylonitrile (AN-HPMA) or HPMA and of N-tertbutylacrylamide (N-TBA) or HPMA and acetoacetoxyethyl methacrylate (AAMA), and at least one biocompatible, water-miscible solvent. The claim further stipulates the limitation that if AN-HPMA is selected, then dimethyl sulfoxide (DMSO) is not used as the solvent.

The teachings to Nakashio et al. with regards to claims 1-4 are discussed above. Nakashio further teaches that the aforementioned ethylenic polymer may be present from about 5-90% by weight of the composition. Formation of the practiced composition as a dispersion or a solution is also taught (col. 3, lines 29-39).

Nakashio does not expressly teach a copolymer of HPMA and acrylonitrile present in the percent range, as claimed by Applicants. Since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. Adjusting the percent composition of the HPMA and acrylonitrile in the practiced composition of Nakashio et al. in order to achieve the desired

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final composition is well within the purview of the skilled artisan. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.

The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615